



21 Roszel Road
P.O. Box 5226
Princeton, NJ 08543-5226
609.924.0808 main | 609.452.1888 fax
www.hillwallack.com

January 8, 2020

VIA ECF

The Honorable Douglas E. Arpert, U.S.M.J.
United States District Court
Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: Par Pharm., Inc. et al. v. Sandoz Inc.
Civil Action No. 3:18-cv-14895-BRM-DEA

Dear Judge Arpert:

This firm, together with Brinks Gilson & Lione, represents Defendant Sandoz Inc. ("Sandoz") in the above-captioned suit. Sandoz respectfully requests leave to amend its invalidity contentions to add one new prior art reference. Plaintiffs have stated they will not oppose Sandoz's request.

The amendments to Sandoz's invalidity contentions are directed to a prior art Lithuanian patent that Sandoz first discovered in November 2019. Good cause exists for Sandoz's proposed amendments under Local Patent Rule 3.7 because Sandoz diligently sought leave to amend its contentions and because the amendments will not cause any prejudice to Plaintiffs.

Sandoz provided a draft of its amended invalidity contentions to Plaintiffs when it sought and received Plaintiffs' statement that they would not oppose Sandoz's request. Sandoz's amended invalidity contentions contain confidential information and Sandoz will provide a copy to the Court at the Court's request. A proposed order granting Sandoz leave to amend is attached as Exhibit A.

I. GOOD CAUSE EXISTS FOR SANDOZ'S AMENDED INVALIDITY CONTENTIONS.

Leave to amend infringement contentions may be granted "by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. Good cause "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted." *AstraZeneca AB v. Dr. Reddy's Labs., Inc.*, No. 11-2317, 2013 U.S. Dist. Lexis 36779, at *8 (D.N.J. Mar. 18, 2013). This Court has recognized that "Rule 3.7 'is not a straitjacket into which litigants are locked from the moment their contentions are served.'" *TFH Publ'ns, Inc. v. Doskocil Mfg. Co.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010) (permitting amendment).

Sandoz became aware of Lithuanian Patent LT 4487 ("LT 4487"), as well as an English translation of that patent, in November 2019. LT 4487 was one of several prior art references that

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came to Sandoz's attention at that time. Sandoz diligently reviewed the collection of prior art and identified the particular relevance of LT 4487. On December 13, 2019, Sandoz informed Par that it would request leave to amend its invalidity contentions and sent the proposed amended invalidity contentions to Par on December 16, 2019. On December 19, 2019, Par stated that it would not object to Sandoz's amended invalidity contentions.

Both the Local Patent Rules and the case law interpreting those rules recognize that Sandoz should have the opportunity to amend its contentions to advance theories of invalidity based on this newly discovered prior art. Local Patent Rule 3.7 provides a non-exhaustive list of examples that may support a finding of good cause, including "recent discovery of material prior art despite earlier diligent searches." *Amgen Inc. v. Kashiv Biosciences, LLC*, No. 18-3347, 2019 U.S. Dist. Lexis 183789, at *6 (D.N.J. Oct. 24, 2019). "[D]iligence is not 'a draconian requirement of perfection and clairvoyance.'" *Abraxis BioScience, LLC v. Actavis, LLC*, No. 16-1925, 2017 U.S. Dist. Lexis 73400, at *7 (D.N.J. May 15, 2017). Despite its best efforts to search for and identify all relevant prior art, Sandoz was not aware of this foreign language prior art reference at the time of its initial invalidity contentions. Upon learning of it, Sandoz promptly informed Par and sought leave to amend its contentions. On these facts, Sandoz acted diligently and has demonstrated good cause to amend its invalidity contentions. *See Abraxis BioScience*, 2017 U.S. Dist. 73400, at *9 (determining that a delay of about four months to review, investigate, prepare, and serve amended contentions is "timely").

II. PLAINTIFFS WILL NOT BE PREJUDICED BY THE PROPOSED AMENDMENTS.

The proposed amendments will have no effect on the deadlines in this case. Fact discovery is still open and opening expert reports are not due until March 2020. *See Amgen*, 2019 U.S. Dist. Lexis at *8. For at least these reasons, Sandoz's amended contentions would not cause any prejudice to Plaintiffs. Plaintiffs have confirmed that they do not object to Sandoz's amended contentions.

* * *

Because Sandoz diligently sought to amend its contentions, and because those contentions will not prejudice Plaintiffs, good cause exists for Sandoz's proposed amendments to its invalidity contentions.

For the foregoing reasons, Sandoz respectfully requests that the Court enter the order attached as Exhibit B granting Sandoz leave to amend. Thank you for Your Honor's kind attention to this matter.

Respectfully submitted,

/s/ Eric I. Abraham
ERIC I. ABRAHAM

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cc: All Counsel of Record (via ECF and e-mail)